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The Pharmaceutical Industry

Drug Pricing Policy & Production

A Study

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DRUG PRICING POLICY & PRODUCTION A STUDY

IMBALANCE IN PRODUCTION & PRICING POLICY

Drug pricing is a highly sensitive, complex and controversial subject on which much interest has been shown in India in recent times, judged by the numerous letters and articles published in the Press from time to time and the frequent Parliamentary debates, questions and answers being reported upon.

In all these exercises and discussions, however, which are often surcharged with emotion, two diametrically opposite positions are clearly discernible.

One which is the more widely held view is that allopathic drugs in India, despite price controls, are excessively priced, beyond the reach of the common man, especially in the rural areas. Even though the production value of basic drugs and formulations together has very nearly touched an all-time high of Rs. 475 crores per annum now, compared to a mere Rs. 10 crores per annum in 1948, the *per capita* consumption of drugs in India is still very low—less than Rs. 7 per annum, against Rs. 100 to Rs. 200 per annum in the developed countries, while the population covered is just 20 per cent. This imbalance in the production and distribution of drugs in the country, it is said, is mainly due to foreign monopoly which, through its control of production, technology and the market, not only smothers the growth of indigeneous enterprise within, but also deprives the common man of essential medicines at cheap prices. In fact, foreign monopoly, through its links with the medical profession, is stated to be interested in catering mostly for the needs of the urban elite who can afford any price for their drugs. A recent UNCTAD study of the pharmaceutical industry in the Third World by Dr. Sanjaya Lall, of Oxford University, highlighting some of the alleged malpractices of the multinationals such as transfer pricing, appears to have added fuel to the fire.

This apart, even according to the statistics of the Organization of Pharmaceutical Producers of India (OPPI) representing the organised large-scale sector of the industry, including the multinationals, the

foreign sector (comprising 51 units) is seen to control as much as 56 per cent. of the production value of bulk drugs and 53 per cent. of that of formulations, while the indigenous large-scale sector (comprising 65 units) and the small-scale sector (comprising over 2,500 units) account for only 9 per cent. and 8 per cent. respectively of the total production value of bulk drugs and 20 per cent, each of that of formulations. What is more, the two public sector units namely, the Indian Drugs and Pharmaceuticals Ltd. (IDPL) and the Hindustan Antibiotics Ltd. (HAL)—which have been assigned a commanding position to reach and control over a third of the total investment (of Rs. 225 crores) in the industry now—have a production value of only 27 per cent. in basic drugs and as little as 7 per cent. of that of formulations.

In this situation, the argument goes on, even if the production of drugs and pharmaceuticals in the country were to be doubled, which, incidentally, has also been the demand of the organised sector, having regard to the targets set under the Fifth Plan and the fast growing population, there would be no guarantee that the common man would reap the benefits of modern drugs at cheap prices, so long as the existing imbalances in the production technology and distribution of drugs as between the different sectors of the industry are not set right. While overall, even a doubling of production of drugs will only result in a *per capita* availability of not more than Rs. 12 to Rs. 14 per annum and a population coverage of not more than 40 per cent, mass consumption of essential, life-saving drugs at relatively cheap prices, however, will not be possible unless the growth of the foreign sector is "blunted", if not ended. The majority view of the Hathi Commitee, recommending the nationalisation of the foreign drug units, reflects this position.

The opposite view, generally held in the industry circles, is that the prices of prescription drugs in India, far from being high, are, in fact, among the lowest in the world, that the imbalance, if any, noticed in the production and distribution of drugs in the country is *not* due to foreign monopoly (the present phenomenal growth of the industry being really due to the notable part played by foreign capital and technology), but to the various unrealistic policy constraints in the matter of licensing, expansion, allocation of raw materials, pricing, etc. based on a segmented approach as between the different sectors regardless of their capabilities, instead of being based on a total view of the industry as a whole which, in the final analysis, is the only

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enduring means of bringing about a sustained overall growth and better distribution as well. The cumulative effect of all these constraints and restraints is stated to have been lesser investment in the industry which, in recent years, has dwindled from an annual average of Rs. 19 crores between 1962 and 1969 to Rs. 8.7 crores between 1970 and 1973 (the period, incidentally, of the operation of price control)and lesser profitability for the industry which today is stated to be not more than 5 per cent, on turnover, as against the prescribed ceiling of 15 per cent. According to this view, therefore, only an uninhibited growth of the industry, without any sectoral biases and prejudices based on foreign and Indian ownership, removing in the process the existing shackles and controls in respect of licensing, expansion, allocation of essential raw materials, etc. and above all, based on a more rational pricing policy which will provide enough funds for plough-back is the real answer to the problem of providing cheaper drugs to the common man, quantitatively and qualitatively.

The Government of India, however, judging from the recent pronouncements of its spokesmen, appears to have steered clear of these two positions and adopted a middle-of-the-road policy, as it were, and rightly so. While strict surveillance will, no doubt, be maintained on the activities of the foreign sector units, they will not be shackled and smothered and much less taken over as such. Rather, their expertise in technology, production, quality control, etc. is to be fully exploited and utilised to the country's advantage. Even while giving full scope and encouragement for the indigenous sectors—public and private, large and small—to grow to greater dimensions, both in terms of investment and share in production, as laid down in the Plan, expansion of the foreign companies is to be allowed under three conditions: (a) they dilute their foreign equity in accordance with the guidelines given under the Foreign Exchange Regulation Act; (b) they give 50 per cent of their additional drug production to indigenous formulators; and (c) 30 per cent of the additional output is exported.

The companies concerned generally appear to have accepted this position and also agreed to supply the essential, life-saving drugs of mass consumption (117 having been identified as such by the Hathi Committee) at special concessional rates.

The crucial question, however, is whether the needed expansion and diversification will take place and, if so, what is going to be the pricing policy of the Government to give a boost to the production of bulk drugs which is basic to the accelerated production of formulations of

varying therapeutic efficacy at cheaper prices, to meet the expanding needs of a growing population. As it is, the imbalance in the Indian drug industry today is not so much in the respective shares in production as between the foreign and Indian sectors, important though it is, as it is between bulk drug production on the one hand and formulations on the other. The total bulk drug production in India now is of the value of about Rs. 75 crores, which gives a turnover of over Rs. 400 crores in formulations—a nearly 1 to 5 ratio. The Rs. 75 crores worth of bulk drugs, however, are made up of raw materials available in the country and imported bulk drugs and intermediates with a foreign exchange content of Rs. 47.50 crores—exactly 50 per cent of the value of bulk drugs in terms of foreign exchange or 70 per cent in terms of landed cost even if the Customs duty is computed at an average of 40 per cent (which is on the low side). The fact, however, remains that the prices of medicines cannot be brought down, unless there is a tremendous increase in the domestic production of bulk drugs. Of about 400 bulk drugs required in the manufacture of formulations, only about 100 bulk drugs are now produced in the country and quite a number imported at considerable cost. Thus, in 1974-75 for example, 163 bulk drugs were imported at a cost of Rs. 31.34 crores, while according to the Hathi Committee, imports of bulk drugs to supplement indigenous production were to the tune of Rs. 14.55 crores in 1971-72, Rs. 10.90 crores in 1972-73 and Rs.10.28 crores in 1973-74. The target set for the Fifth Plan is to increase bulk drug production by three times, to about Rs. 200 crores or so by 1978-79. If the Plan target is to be achieved, heavy investment in bulk drug production which is highly capital-intensive, with a long gestation period, and in which the investment-turnover ratio is around 1:1, cannot brook any more delay. The manufacture of formulations needs much less capital, where the corresponding ratio is about 1:2.6, but can rise as high as 1:7.6.

The existing drug price control system, however, which provides a maximum return of 15 per cent on capital employed for bulk drugs and a mark-up of 75-150 per cent of manufacturing costs for formulations, with an overall profit ceiling of 15 per cent on sales turnover, has a clear, built-in disincentive to drug production as against formulation activity where the profitability ranges between 2.6 to 7.5 times the capital employed. Thus, conceivably, as has been aptly said, "not only can a formulator make a lot more than a drug maker on every unit of capital he employs, but the higher the turnover the higher

is his profitability in relation to capital employed". No wonder, therefore, that the units in the private sector (not merely multinationals) are prone to taking to more and more of what is called "low technology, high profit" formulation activity. In reality, however, as the Hathi Committee has unequivocally stated, "the general inflationary tendency and more particularly the recent steep escalation in some of the cost inputs and manufacturing expenses which have only been partially compensated in the form of an adjustment of prices has, in effect, meant that the (profit) ceiling of 15 per cent on sales turnover...has become *notional* for most units of the industry". Thus, according to the figures furnished by this committee, the pre-tax profit as a percentage of turnover (for an aggregate of 58 firms) declined from 15.47 per cent in 1969-70 (the year prior to Drug Price Control) to 10.19 in 1971-72 and still further to 8.53 per cent in 1972-73 (Drug Price Control period). According to other sources, this ratio was only 8.00 per cent in 1973-74 (for an aggregate of 39 companies), 5.74 per cent in 1974-75 and below 5 per cent in 1975-76 (for an aggregate of 27 companies in both the years).

True, these aggregate statistics for the whole industry (comprising the foreign sector, the Indian sector, the Public and the small-scale sector, while showing lesser profitability overall, do not reveal the full picture because it is possible that although many units are making small profits and others are incurring even losses, there are still others who are making good profits. Thus, the latest study of the Reserve Bank on foreign companies (1974) has revealed that the profitability figures in relation to capital employed are not only high for the pharmaceutical industry but are noticeably higher than for others (with a range of about 10 per cent above). The company statistics published in the Reserve Bank Bulletin, September 1975, also confirm this trend for the industry during the period 1970-71 to 1973-74. These relatively high profit ratios of the companies can partly be explained by their diversification into such allied spheres as pesticides, chemicals and dyes, which are nevertheless important and useful to the economy. This, incidentally, perhaps explains why, despite the low profitability for the industry as a whole, the official drug price index has risen far more slowly than the wholesale price index for the essential commodities. Thus, while the wholesale price index rose by 152 per cent in August 1973 (with base 1961-62=100), the drug price index rose by only 48.7 per cent. Even when the commodity price index touched an all-time high of 328 points in September 1974

(recording an increase of 31 per cent in one year), the corresponding increase (in October 1974) in the drug price index had been only 175 points (an increase of about 26 per cent in two years.)

Public Sector

The public sector units, however, whose manufacturing activity is heavily geared towards the less profitable bulk drug production have laboured under two kinds of difficulties, namely, unremunerative prices under price control in an environment of rising costs and technical and technological problems which have bedevilled their performance, over the years, leading to considerable under-utilisation of production capacity. The recent disclosures in this regard on Hindustan Antibiotics made by the Parliamentary Commitee on Public Undertakings have, indeed, greatly disturbed the public mind. When the HAL was established in 1954, the cost of producing penicillin in the country was estimated at one-third price of imported penicillin. But, on account of control on selling prices, the production of penicillin and Streptomycin virtually stagnated during the period 1959 to 1967, causing a serious financial setback to the unit, What is more, in the words of the Parliamentary Committee, "in spite of formulations being a profitable proposition, the undertaking did not make any attempt to increase the capacity for formulations". Even the IDPL which accounted, in 1972-73, for 44.5 per cent, 34.4 per cent and 80.8 per cent respectively of the overall licensed capacity for the three important bulk drugs, namely penicillin, Streptomycin and Tetracycline, could only produce 19.8 per cent, 12.8 per cent and 27.1 per cent respectively of the total output of these drugs, while, in 1973-74, its capacity utilisation in this behalf dwindled further to 46 per cent, 24 per cent and 64 per cent respectively. Inevitably, both the public sector units have had to sustain a cumulative loss of over Rs. 42 crores as in March 1974, and the country has been compelled to import bulk drugs to meet its minimum essential requirements to the tune of nearly Rs. 70 crores during the last five years or so.

During the last year or two, however, the State-owned units appear to be coming up well, having largely got over their technical problems. Thus, while the sales turnover of the IDPL rose to Rs. 20 crores in 1974-75 from Rs. 12 crores in the previous year, its net profit (after depreciation and interest) increased more than four

times to Rs. 4 crores. Its performance in 1975-76 is reportedly even better having achieved an all-time high production of Rs. 61 crores, though its net profit dwindled to Rs. 2.73 crores, Similarly, it is hoped that HAL would attain a sales turnover of Rs. 15 crores during the year and make profits. But this improvement in the situation appears to have been brought about largely by the price hikes granted to the units to neutralise the cost escalations in the context of persistent underutilisation of capacity, on the one hand, and continued losses sustained over the years, on the other. In fact, under the present cost structure, the managing director of HAL is reported to have stated that the unit cannot attain the break-even point even by utilising 100 per cent of its installed capacity, so much so 45 per cent of its basic drug production is being used for its own formulations so as to gain some margin at the market. The need of the hour, however, is increased investment, in which the progress made so far does not seem to be encouraging. Thus, of the projected outlay of Rs. 70 crores provided for the public sector in the Fifth Plan, what had been actually spent in the first two years of the Plan, as disclosed in the Budget for 1976-77, is precisely Rs. 7.12 crores !

On the other hand, the production of drugs in some of the private sector units has been more than the licensed capacity, as 'The Economic Times" study published last year (January 20/21, 1975) has revealed. This has raised the problem of "excess" production, needing regularisation. One wonders whether in the context of the relative failure of the public sector to deliver the goods, such an outcry of over-production against the private sector is at all relevant especially when the need of the hour is production of drugs by leaps and bounds, The result has been that the companies concerned have been forced to cut down their production. For example, Pfizer's output of bulk drugs really declined to 195 tonnes in 1973 from 206 tonnes in 1972, against its installed capacity, on a three-shift basis, of 271.75 tonnes and its licensed capacity of 205.8 tonnes. Cyanamid, again, is allowed to produce Tetracycline only up to its licensed capacity of 10 tonnes against its installed capacity of 18 tonnes, while 60 tonnes of the same drug are being imported. Thus, it seems essential, as The Economic Times study has averred, "that the Government should regularise the excess capacity to ensure uninterrupted production and thereby drastically reduce imports. The recent paradoxical situation of scarcity of popular brands of medicines, on the one hand, and the mounting inventories with the STC and

the IDPL, on the other, is mainly due to imbalance in indigenous production."

Be that as it may, in fairness to HAL and IDPL, however, it should be said, as indeed the Parliamentary Committee has done, that while the cost of production of various bulk drugs and formulations produced by them has more than doubled itself since 1966-67, thanks to price control, the selling prices on most of these products have been much below the cost of production. This is again because of another paradoxical situation, by which the end-prices of drugs are controlled, not so the input prices which are allowed to escalate, thus causing considerable distortion in the pricing structure, especially in the context of gross underutilization of production capacity in the public sector on the one hand, and strictly controlled production in the private sector on the other, not capable of reaping the benefits of economies of scale. No wonder, therefore, that the price of Vitamin C, for example, is Rs. 113.51 per kg. in India, against Rs. 50 in Europe; that of Chloramphenicol is Rs. 524.69 against Rs. 200; Tetracycline Rs. 650 and Rs. 200; Oxyphenybutazone Rs. 1,002 and Rs. 400 respectively.

II

HIGH COST STRUCTURE & PRICE DISTORTIONS

Research and development and the availability of technology in the drug industry have a great bearing on the domestic costs and prices of our drugs.

In this connection, a distinction needs to be drawn between the development of a new drug and improvement in the know-how or development of more sophisticated technology. The first is, indeed, an extremely costly and complex process, involving long gestation periods as well. The cost of the minimum functional size of a research unit in the drug industry is estimated to be of the order of Rs. 3 to 5 crores, with an annual recurring cost of Rs. 1 crore. No wonder, therefore, only eight Indian institutions, including the public sector units and the national laboratories could now maintain fairly well-equipped research facilities in different classes of drugs, while only six Indian firms, which have a sizable turnover, have taken some steps towards developing basic innovational research.

However, in spite of heavy investment, period of operation and the man-power involved, we have not had the benefit of any new breakthrough or discoveries so far.

Improvement of know-how or development of more sophisticated technology is, thus, a gradual process and here, the multinationals have a lead insofar as they have developed quicker and cheaper methods of production for most of their drugs. In fact, some of the bulk drugs which the IDPL manufactures now were first introduced in the country by the foreign sector. In the case of Streptomycin, for example, manufactured by both the HAL and Merck Sharpe Dohme, the latter uses more sophisticated technology which tends to bring down costs. Even the IDPL, despite its being a monopoly producer of several bulk drugs like Sulphanilamide, Sulphadimidine, Analgin, Phenobarbitone, has not been able to steal a march over the private sector counterparts in introducing new drugs because of the several manufacturing inefficiencies such as the imbalance in the production capacity of bulk drugs and formulations, which has been a persistent feature of its operations. On the other hand, Cyanamid (India) has switched over from Chlorotetracycline to Demethychlorotetracycline; while Pfizer (India) has been pushing its product Terramycin (Oxytetracycline) in preference to Tetracycline and has also gone a step further in introducing Detracycline (another improved product). Another factor in their favour is that the parent company's research and technical know-how is available to them free of cost (as for example, in the case of Pfizer, Roche and Richardson).

Thus, the technology and know-how for producing highly sophisticated drugs and formulations being complex and the rate of technology obsolescence in the industry being very high, it seems necessary for us to continue to have access to foreign technology, particularly in the matter of new drugs, for quite some time to come. While the indigenous sector at present just does not have the resources, the know-how and expertise enough, India cannot afford to wait indeninitely or live in isolation from the rapid and sweeping technological developments taking place abroad. The Government, therefore, seems just right in feeling that the foreign expertise should not be shunned, but should be utilised to the country's full advantage.

This does not mean, however, that the existing technology available with the indigenous sector is unserviceable or should not be improved upon. While adaptive research, process and product development should no doubt be pursued vigorously for obtaining the maximum

results, "copying" of drugs and formulations made possible by the Patents Act of 1970 (which has reduced the patent period of a drug to just seven years) also seems to be an avenue of good potential. What is needed most, however, is to have a worthwhile liaison, which does not seem to exist now, between the HAL, the IDPL and the various national laboratories and research institutes, both in the public and the private sector, so as to enable a fruitful exchange of technology and research on a mutually beneficial basis. Such an exchange will not only help to bring about an optimum utilisation of existing production capacity in the country, both in respect of bulk drugs and formulations but also high technological competence and capability for the country as a whole, thus leading to a massive production of essential drugs at relatively cheaper prices, while arresting the present outflow of precious foreign exchange for the import of these drugs.

Ad hoc increases in drug prices granted, from time to time, however, to prop up mainly the public sector units (without substantially improving their technological capability), which have incidentally also helped the private sector units in getting higher prices for their products, have not been of much help to either. Such ad-hocism, without any attempt at fitting the price structure into any rational pattern, either over the short-term or long-term and thus introducing a measure of stability in the system, has also not helped the consumer to get cheaper drugs nor the industry (including the public sector) in evolving a long-term strategy for future growth. On the other hand, input prices chasing drug prices and vice versa have only made the essential, life-saving drugs for the common man being priced out, thus resulting in frequent drug shortages in the country and giving a free hand for the growth of spurious and sub-standard drugs as well.

Incidentally, a word here would be appropriate on the small-scale sector, the proliferation of which has been allowed to such an extent that it poses a challenge to the drug control administrations in various States in enforcing standards and quality. There is no denying the fact that in a country of India's size, population and factor endowments, small scale units providing scope for self-employment do have a place, but only in areas most suited to them (eg. manufacture of pharmaceutical aids, excipients, intermediaries, raw materials and accessories, packaging materials, certain types of machinery, etc.). One potent way of restructuring the small-scale

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sector would be for the public sector units to sub-contract some of their formulations to the small-scale sector, which, incidentally, may help to boost their sales as well.

The irrational method of pricing based on the 'cost-plus' principle, however, appears to have brought about the opposite result of hiking the prices of common medicines and household remedies which have a larger turnover than those of life-saving drugs produced mostly by the public sector units. It is no wonder, therefore, in this context, as reported, that a 450 gm. bottle of Ferradol (Parke Davis) costs now Rs. 8.15, against Rs. 6.54 in 1971: a 28 gm. bottle of Iodex (SKF) has gone up from Rs. 2.90 to Rs. 3.35 and a bottle of 500 tablets of Saccharin (Boots) from Rs. 2.13 to Rs. 4.20, while the IDPL's Calwod tablets (100) are sold for Rs. 6.90 against Rs. 9 to Rs. 15.69, in which range similar products produced by Roche, Lamedica and Ranbaxy are sold; its Chloroquin Phosphate tablets (500) cost Rs. 42.75, against Rs. 65 for the same number of Bayer's Resochin, and its price of the Compeba tablets (100) *is Rs.* 18.64 against *Rs.* 38 of May & Baker's Flagyl. These relatively lower prices of the IDPL's products, however, it should be noted, are not **economic** prices, based on optimisation of capacity and output, but are largely in the nature of "**distress prices**" in the context of the pronounced under-utilisation of capacity and the losses sustained over the years. Much less can it be said that the higher prices of the private sector products quoted above are rational and reasonable, having regard to the due play of competitive forces in the country, had the irrational price control system based on escalating costs of production not been in vogue.

There are two other factors as well causing considerable distortion in the pricing structure. One is excise duty, which is often erratic in its incidence, following each successive Budget of the Government of India. Thus, following the increase in excise duty on patent and proprietory medicines from 7.5 per cent to 12.5 per cent, and that on alcoholic and narcotic drugs from 10 per cent to 15 per cent, as announced in the Union Budget for 1966-67, drug prices have reportedly gone up further. The relief to the common man, therefore, is far from being in sight. The other is the canalisation of the import of drugs through the STC and the IDPL, adopted mainly with the idea of curbing the tendency of the multinationals to import basic drugs at high prices from their principals and collaborators abroad. "But", as "The Economic Times" study has revealed, "it

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is doubtful whether the pooled price system has enabled the ultimate consumer to procure drugs at cheaper prices...A comparison of the pooled price of drugs with the imported price of bulk drugs indicates that the pooled prices of drugs supplied by the public sector are higher. The disparity in the pooled prices vis-a-vis c. i. f. prices, in fact enabled the IDPL to make a gross profit of Rs. 219 lakhs in 1972-73 against Rs. 169 lakhs in 1971-72." All these costs, it should be remembered, are added on to the cost of the final product. Although the Government has recently proposed to cut down the margin of the STC and the IDPL on imported drugs, how far such a cut will really help to bring down the final cost of the drugs remains to be seen.

It is to the credit of the Hathi Committee that, after careful consideration and study of all these various aspects, it has made certain radical departures in the concepts and methodology followed in drug pricing so far. The Government, however, has not yet announced its decision in this regard. All the same, an objective analysis of the whole issue of drug pricing, with special reference to the Hathi Committee's recommendations, and how the concepts and mechanics involved could be rationalised so as to bring about an accelerated growth of the Industry, while meeting the massive needs of the common man for drugs of various kinds at relatively cheap prices, over the long-term, seems necessary and appropriate. This is what is attempted in this series of articles.

Rationale and objectives of price policy : Even in the most advanced countries, the pharmaceutical industry is closely watched, regulated and controlled by legislative, fiscal and other measures, the idea being that no one should profiteer from the people's ill-health. In a country like India, however, where the per capita income is only about Rs. 342 (at 1960-61 prices) and the per capita expenditure on medicines is less than Rs. 7 per annum and where there is no State organised or State-sponsored health scheme on a comprehensive basis, as in the United Kingdom, for example, which would absorb the rising cost of drugs while meeting the full health needs of the people, it goes without saying that the prices of essential and life-saving drugs should be within the reach of the average man's purse. This, in short, is the rationale behind drug price control.

Price is, indeed, the fulcrum or pivot round which revolves the entire mechanism of production, distribution and consumption and thus plays a crucial role in the regulation of the entire spectrum

of economic activities. While protecting the interests of the consumers, the objective of a rational price policy should also be to see that a healthy industry is not turned into a "sick" one over a period of time, thereby paralysing its production, marketing and distribution base and threatening its very existence as it were, not to mention meeting its growth requirements. In other words, the price policy should not only help to bring about an uninterrupted availability of high quality drugs at reasonable prices to the consumer, but also ensure a reasonable return to the producer so as to give an impetus to growth, by which not only the existing units would be enabled to function more economically and efficiently but, what is more, new investments and new units are attracted to strengthen the production base so that the long-term objectives of economic growth through an increase in savings and investment are subserved and realised.

The question, however, is what is the **fair** or **just price** which would balance the interests of the consumer and the producer alike as well as of the socio-economic community at large. The question of **fair** price, indeed, assumes importance primarily from our social objectives. One of the serious problems facing the country today is how to cut down costs through continuous improvements in technological, managerial and other efficiencies, especially in an economy with its high cost structure and bias towards the sellers' market. In this context, the social consumption of the many rather than the individual consumption of the few, in respect of the many necessities of life of which drugs and pharmaceuticals are among the foremost, becomes a paramount objective. In other words, the cost to the community as a whole rather than to a reliatively few individuals or sections of the population gains precedence in any scheme of administered pricing. Cost reduction, therefore, through innovation and improved technology and also through a dip in the rate of return, is a 'must'. Our social objectives demand it.

In normal circumstances, the price of any commodity is determined by the forces of demand and supply. The competitive economy is like a delicate machine in which every part is so closely interrelated that the breakdown of a minute part sets the forces of correction in time to save the entire machine. The built-in forces act as a kind of economic safety valve issuing warnings in time so as to prevent the mechanism from utter collapse. In riskless perfect competition, however, the uniformity of the profit rate is a condition which re-

flects the true nature of pricing as representing its cost and demand structure when all elements of shortage value or rent of scarcity or distortions by taxation or monopoly have been eliminated. Granted that technological, managerial and other efficiencies are optimised so that economic growth in terms of quality, quantity, delivery and price has reached a stage of near-perfection, in such a hypothetical situation, however remote it may be from us now, the prices could be expected to be such that what the market **could** bear may be equal to or less than what the market **should** bear. In other words, the supply curve of a commodity is dependent upon the conditions of its own demand and that of other goods, while the demand curve depends upon the conditions of production and supply of all goods in the economy. This inter-relationship between demand and supply of a product and its linkage with the demand and supply of other products invalidates the traditional theory of the demand and supply curve being independent in their interaction, uninfluenced by the markets of other products. The same considerations vitiate the theory of pricing for individual firm as well.

Even according to the traditional analysis, the high price of a product would tend to raise the rate of profit in the industry producing the commodity in shortage, attracting further investments into this line rather than in others, while the industries with a lower rate of profit would not get the normal amount of new investments flowing into them. Thus, these two tendencies together redress scarcity and glut in the respective industries and bring back the prices to the normal level, reflecting the technical conditions of production through inputs needed and their productives. The **equilibrium price-vector** is thus the set of prices which will rule when the elements of sellers' or buyers' market have been eliminated from the system. Perfect competition, therefore, tends to eliminate, by establishing a uniform rate of profit, the rent factor on account of scarcity of particular goods in relation to the abundance of other goods.

Economic planning, however, provides the mechanism of allocation as a substitute for perfect competition and for keeping the system in equilibrium and enabling the enterprises to choose the appropriate investment techniques, seeks to fix a set of prices which would perform the purposes of the right choice of techniques and the right amount of investment which competitive prices with perfect knowledge of the present, the past and the future are supposed to do. Thus, when the investment allocations are placed in equilibrium

appropriate to the technology, wage-rate and propensities of entrepreneurs to consume the price that will be compatible with keeping the economy in a state of balance of demand and supply of all goods are the **shadow** prices, while the **actual** prices are those that deviate from the shadow, on account of scarcity or glut, the degree of deviation depending upon the degree of abnormality in the price structure. In other words, the shadow prices mirror the technical reality after the veil cast on actual prices by mal-allocational deviations from normality have been lifted. In this sense, the actual prices are clouded by the haze of illusion and shadow prices are the true reflection of reality. A study of the technical conditions of input and output in the economy as a whole showing the interaction of activities is, therefore, fundamental in any price analysis.

III

METHODOLOGY FOR FIXING PRICES IN DRUG INDUSTRY

Price fixation in a developing, mixed economy, with its own inbuilt contradictions, is a highly complicated, responsible and judicious task and should be based upon a good deal of empirical study and analysis of the factors and forces involved.

The exercise in drug price control in India is now 13 years old. Until 1963, the prices of drugs were left to be determined by the forces of competition which no doubt enabled the industry, during the initial, formative period of its growth, to introduce many new drugs in the field of antibiotics, anti-TB drugs, hormones, vitamins, etc. and which, relatively speaking, tended to bring down their prices as well for the benefit of the consumer. A kind of price freeze came into vogue in 1963, soon after the Chinese aggression, by which the prices of drugs and formulations were pegged at the existing levels, preventing their further rise without Government approval. There was, however, no machinery for reviewing or rationalising drug prices from time to time. Thus, between 1963 and 1966, very few revisions of drug prices were entertained though the industry was clamouring for increases on the ground of cost escalations in respect of raw and packaging materials, wages, administrative and other expenses, etc. Some units even discontinued the supply of medicines

at special rates being made to the Government hospitals.

In 1966, however, the Government issued an Order under the Essential Commodities Act, stipulating that no new product or formulation should be marketed without its approval in regard to prices. At the same time, the Government requested the Tariff Commission to review the cost structure of 18 essential bulk drugs and their formulations (69 of them). The Commission submitted its report to the Government, after two years of inquiry and deliberation, in 1968. Based on the recommendations of this body, the Government announced the Drug (Prices Control) Order in May, 1970, which now governs the operative mechanism of drug pricing in the country. Almost immediately thereafter, the Government referred to the Bureau of Industrial Costs and Prices the cost and price structure of 25 more drugs and the mark-up of formulations not dealt with by the Tariff Commission.

The methodology in drug pricing as adopted both by the Tariff Commission and the BICP and currently followed by the Government under the Drug (Prices Control) Order 1970, has remained the same. The cost of production is the prime concept, based on which a return is added to get the price. Only the basis of computing the return to the industry for bulk drugs and formulations is different, the one based on capital employed in business and the other on sales turnover. The Tariff Commission has adduced the reasons for providing this differential basis of computing the return to the industry as under :

"In the case of activity related to the manufacture of basic drugs, heavy capital investment is needed and Return, therefore, can be related to the capital employed. On the other hand in the case of formulations, the industry and consequently the individual units are not capital-intensive and the proportion of capital employed to sales turn-over is very much smaller than in the other case. While it would be quite safe to adopt the capital-employed basis in the case of basic drug manufacture, in the case of formulating activity, the rate of profit cannot be so applied to the employed capital, since the quantum of net assets is small and working capital high. The determination of the working capital in the case of formulating activity would be difficult and even if it is done it will be more or less tantamount to the cost of sales."

Thus, under the existing price control system, while a 15 per cent. return on capital employed (pre-tax) is allowed for bulk drugs, a

mark-up of 75 to 150 per cent. is permitted on the manufacturing cost of formulations which consists of: (a) material cost (which includes cost of basic drugs and pharmaceutical aids), (b) conversion cost (which includes conversion charges and overheads), and (c) packaging cost.

Seventy-five per cent. mark-up is allowed on the manufacturing cost in respect of existing and ordinary drugs; a higher mark-up of 100 per cent. for a period of three years in respect of new products evolved as a result of special product development work and 150 per cent. mark-up for a period of not more than five years for new drugs produced out of original research and containing new therapeutic ingredients. It is, however, the industry's complaint that the mark-ups actually allowed have been far less (not more than up to 70 per cent.) than what has been provided for under the Drug Price Control Order.

An alternative scheme of pricing, however, provides that formulations based on bulk drugs other than the essential bulk drugs would be priced, in accordance with the pricing formula, subject to the mark-up in any individual case not exceeding 150 per cent. However, such prices should be so fixed that the overall gross profit of the manufacture before tax would not exceed 15 per cent. of the sales turnover during the year. This alternative scheme gives enough flexibility to adopt a pricing policy suited to the individual requirements of the manufacturers concerned, especially in the small and medium sectors. Also, smaller companies with a turnover not exceeding Rs. 50 lakhs per annum have been exempted from the requirement of obtaining Government approval to the prices of their formulations. Thus, the Government has assumed that "any rational and equitable drug price control system has to take into account this differential price situation and the existence of relative strength of the different types of producing units competing with each other. Consequently, the control system must aim at bringing the leaders' prices down to a reasonable level, while at the same time enabling the medium and small scale units to move up their prices to fair levels where merited, while also providing sufficient room for competitive force to act between the different classes of manufacturers and products."

How far this laudable objective of the Government has been actually realised is, however, a moot point. It is, indeed, difficult to place all the products under one formula. When the Price Control Order

was clamped on the industry, the prices of life-saving drugs had to be cut and the manufacturers made good the reduction in profit by raising the prices of household and established drugs within the ceiling of 75 per cent. mark-up. A large company can certainly market its home remedies or larger turnover products at a lower profit and balance its overall profit with high turnover or against high prices for specialised proprietory drugs. This cushion, however, is not available to the smaller companies, the very size of which prevents them from availing themselves of the economies of scale, while they cannot compete with the larger firms in the matter of productive and technological efficiency as well.

The pharmaceutical industry, in fact, is very different from other industries in that while, in the latter, the cost of wholesale or retail advertising is borne by the retailer or wholesaler, the cost of promotion in respect of prescription drugs, however, is borne entirely by the drug manufacturers who have to bear, among other things, (1) forwarding charges, (2) promotional expenses, (3) after sales service and (4) trade commission right up to the retail level.

The expenditure on these services does not, in fact, have any direct relationship with the capital employed. Hence, the Tariff Commission concluded that it will be quite safe to adopt the cost of sales approach in the matter of fixing the return to the industry in respect of the formulation activity, since "profit constitutes the difference between the value of sales and the cost of sales, and these may be related, (in turn), to the capital employed in order to provide a fair rate of Return to shareholders and to provide funds enough for the discharge of other liabilities imposed on the companies." This broad approach has also been followed by the BICP in regard to the price revisions being made by it from time to time in respect of drugs and pharmaceuticals.

Pit Falls of the "Cost Plus" Basis : The 'cost-plus' basis of price fixation really means that the price will equal the estimated average direct cost of production plus a gross or costing margin. The determination of the price on any cost-based formula, however, involves so many imponderables and variables that the price estimates often tend to go wrong. First, costing itself is rendered difficult for lack of systematic and correct data maintained, especially in the large number of small or even medium units. Hence, necessarily, recourse is made to those units, large and well-established ones, where some system of cost accounting is followed and the data on costs in what-

ever form, are made available. In other cases, if at all, costs are structured by personal discussions or otherwise in the light of the standards given in the text-books. This is a laborious process and is not quite a reliable method either. Secondly, the inadequacy or non-availability of the relevant cost data among a large number of units, big, medium and small, necessarily vitiates the representative character of these data which involve not only a study of the costs as such, but other factors as well, such as productive capacity, efficiency (technological and other), demand (current and future), supply of raw materials and stores, in respect of all of which uncertainties often linger owing to the changing economic conditions and policies of the Government. Thus, if there is a large deviation from the expected figure of production, the allocation of overheads as an element of cost will also go wrong. This is particularly true of wage cost. With a highly unstable price-wage structure, it is extremely difficult to estimate how the rates of payment for the different factors are going to years. In short, the elements that should go to the cost structure are often so varied, elusive, controversial and indeterminate in character that pricing based upon such an exercise calls for a good deal of judicious discretion on the part of the price determining authority.

The cruical question, however· is what is cost and what are the cost elements relevant for pricing. Broadly speaking, cost consists of two main elements (1) fixed costs, such as land, plant and machinery, depreciation and working capital and (ii) variable, such as overheads and distribution costs. These two elements together broadly constitute the **capital employed,** but the concept of capital employed again is a highly controversial concept. While the price determining authorities have one way of computing capital employed as constituing fixed asstes and working capital, the industry has another way by which all such items as bonus, interest, donations, bad debts, goodwill, etc. are included in the cost of capital so as to gain the maximum advantage in pricing. These pulls and pressures are, in fact, inherent in any scheme of costbased, administered pricing, so that the emerging pattern is that individual prices are fixed without any relationship whatsover with the underlying economic conditions or the needs of the industry as a whole. Thus, the prices fixed based on cost of production have often irrational provisions made for rehabilitation, unforeseen cost escalations due to inflation and contingencies considered necessary from time to time, all of which

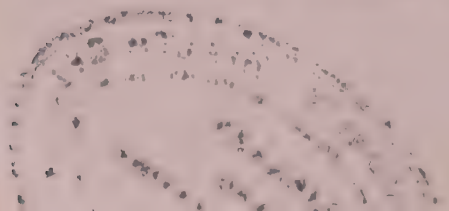
have only tended to inflate costs and prices further. In fact, the cost basis of pricing, far from helping to generate and stimulate demand, tends to curb it, because it fails to stimulate competition in the industry adequately.

What is more, based as it is on the average costs of relatively inefficient marginal units, it tends to penalise an efficient low cost producer as against an inefficient manufacturer who gets rewarded, as it were, for his high cost by being given a higher price for his product.

High costs are already inherent in an oligopolistic economy such as ours, and unless there is a very strong urge on the part of the industry for technological innovation and other improvements which are the only means of cutting down costs, the tendency is for the units to stagnate. This is, indeed, the case with a large number of indigenous units, especially the small scale, jeopardising their viability all the more. The price structure should, therefore, provide for an in-built spur to efficiency all around, so that the widening gap between social and private costs in the economy could be reduced as quickly as possible.

As it is, however, the price determining authority (be it the Tariff Commission, the BICP or any other) bases its prices on the *historical cost* which has no relevance whatsover for the present and future costs. In a going concern, the equipment has to be replaced at periodical interval and the cost of replacement is always higher than the historical cost of the equipment which is replaced. The Economic Survey (1975-76) clearly acknowledges this fact when it says: "There is now considerable evidence that the steep increase in costs of machinery and equipment in recent years is affecting not only new investment but also modernisation and replacement of existing equipment. In a period of rapidly rising prices, depreciation formulas based on historical costs cease to provide adequate resources for replacement of the existing worn-out equipment. Moreover, in industries under price control so long as calculations of permissible rates of Return continue to be based on historical cost of fixed capital in use, there is a built-in disincentive to new investment."

In this context, therefore, it is no surprise, as OPPI has often been saying, that new investment in the pharmaceutical industry has dwindled from an annual rate of Rs. 19.1 crores in the period prior to price control to just about half (i. e. 8.7 crores) in the price control period. "The Economic Times" study (of January 1975), referred to earlier, has also clearly stated that there was a deceleration in the



growth of gross fixed assets (of the industry) which worked out at 9.8 per cent, in 1972-73 compared to 12.1 per cent. in 1971-72 and as much a 25.8 per cent. in 1961-62. The recent trend in the falling share prices of some of the leading pharmaceutical firms also tends to confirm this position.

Arising out of this situation has been a recent trend in drug pricing, namely *different prices* being fixed for the same product (e. g. vitamin C, penicillin and streptomycin), as between different units. The main justification adduced for differential pricing is that the capital cost of a new manufacturer is relatively higher than that of the old one which could be made good only by a higher price granted to the former as against the latter, even though the product may be the same. This method of pricing, however, is clearly irrational for more reasons than one. For one thing, the new manufacturer does not really acquire the same asset at a higher price; what he acquires is an altogether different new asset, capable of much higher production indeed, in terms of technological and other efficiencies. The higher cost of the equipment paid, if any, therefore, is offset by the higher productivity attained. For another, a multiplicity of prices for the same product, based on the cost of production of different manufacturers, apart from being difficult to administer, will cause considerable inconvenience as well to the producer and consumer alike and would only help to encourage and reward inefficiency and make the entire pricing structure highcost all the more, which the country can ill-afford now. The right answer to the problem of replacement costs of fixed assets is thus not *differential pricing,* but perhaps an *investment allowance* as provided for in the Union Budget for 1976-77. In the final analysis, however, the viability of a unit or an industry could result only from efficiency brought about by cost reduction all around, and not by uncurbed profits and high prices at the cost of the community at large.

Thus, the costs relevant for pricing are *not* actual costs (neither past nor present nor absolute nor average costs) which do not point the way to the best nor provide a tool for comparative analysis, not even standard costs which, while emphasising what cost should be at a particular point of time and supplying a technique for diagnozing the effects of pricing policies, do not in themselves form the basis for price fixation, but *differential economic costs* that result from producing and distributing additional or fewer units of a product or from change in the method of production and distribution. In other words,

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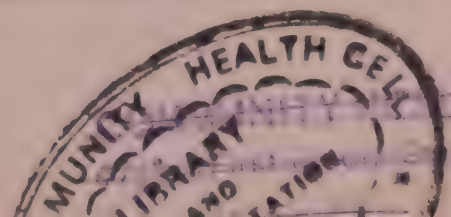


volume, technology, productive, managerial and other efficiencies and, above all, demand have all a vital bearing in pricing which have to be reckoned with in an integrated manner.

IV

BASIS FOR COMPUTING RETURN

A vital question regarding the drug industry is what a reasonable return to the industry is which, again, has to be viewed from the angle of bulk drugs and formulations separately.

Before doing so, certain broad factors governing investment in the industry as a whole merit attention. It should be clear that any potential investor will only choose that area or sector of industrial activity where the return is likely to be the maximum; and this return, again, is directly linked with the element of risk involved in business.

Risk is a situation in which, though the outcome is uncertain, the probability distribution of outcomes is known with a measure of certainty; while the other extreme is where nothing whatsoever is known about the probability distribution and one has to deal with pure uncertainty. Thus, the risk element in the pharmaceutical industry is generally considered to be higher than in other lines of business activity. Bulk drug production is not only capital-intensive but is fraught with high risks and uncertainties as well. Even in the field of formulations, product and process obsolescence is high and rapid, needing frequent replacement. In both these areas of drug production, moreover, research and technology involving heavy capital outlays play a big part in product development.

In this context, the question of capacity utilisation also assumes importance, although there are differences as to the basis of assessing such utilisation—whether it should be limited to the actual installed capacity presently being utilised or it should include the extent to which the capacity can be utilised with reference to future requirements as well. The return, however, has a bearing on all these factors which tend to influence the investment made.

Yet another element entering into the fixation of return to the industry is the prevailing borrowing rate, which has almost doubled itself (to 15-16½ per cent) now from the time the Tariff Commission and the BICP went into the cost and price structure of drugs years

ago. What is more, as a result of the credit squeeze and other restrictive measures adopted in the recent past, many units, especially in the medium and small-scale sectors, have reportedly had to seek finance from sources other than scheduled banks, paying even higher rates of interest. These factors, it is contended, have a more vital bearing on the quantum of return available to the industry than the element of risk itself.

While, thus, in these various ways, return has a direct and vital bearing on investment, a guaranteed return, however, tends to signify that the economic viability of the enterprise is in doubt and that it is unable or unwilling to take the necessary risks involved in business. Even so, the entrepreneur to sustain himself in business should make profits at some risks which have to be balanced against the long range pattern of risks present or anticipated for the firm or the industry. Profit is, thus, not the cause or rationale of business behaviour and business decisions, but the *test* of their validity. Even in conditions of monopoly, selling prices must be adjusted in such a manner as would create a wider demand so that the products reach the masses. Thus, the main aspect of profit is growth. In the words of Dr. W. W. Heller, formerly Chairman of the Council of Economic Advisers to the President of the U. S. A.: "The role of profits in national economic policy is essentially a derived one—derived from the policies of growth for full employment, for price stability, for the balance of payments equilibrium and for equality of economic opprtunity". In other words, while Return or profits is the sum of interest earned on capital employed in business and the remuneration of the entrepreneur for risking his capital, it is also an engine of growth for the economy as a whole.

(i) **Bulk drugs—Concept of post-tax return versus pre-tax return on capital:** The question, however, is what is capital on which the return is to be based. Capital is a concept with different meanings, but they all have one connotation, namely, that it is a *stock* as contrasted with income which is a *flow*. In relation to the production of commodities, however, it is usual to classify capital into two categories, namely, *fixed capital or assets,* consisting of land, buildings and machines and *circulating or working capital* consisting of goods in process, raw materials, stock of finished goods to be sold, etc. The capital used as a means of production, in the case of a manufacturing enterprise, is also expressed in terms of *share capitals, reserves* and *borrowings*. In other words, capital employed in business is equi-

valent to fixed assets and working capital, on the one hand and share capital, reserves and borrowings, on the other.

For a manufacturing enterprise, the capital required (i.e. the means of production) can only be from two sources, namely, the capital subscribed by the shareholders and borrowings. 'Share capital' and 'capital' for the enterprise must be distinguished. An enterprise, to start with, has only share capital, and at that point, share capital is *equal* to capital employed, but later, when the enterprise develops and produces surpluses, share capital is bound to be different from capital employed in so far as the latter gets enlarged by the savings made by the enterprise itself, a portion of which is retained and ploughed back. Thus, both share capital and reserves represent savings, the one from other enterprises or occupations and the other, from the surplus value of the enterprise itself. The distinction between share capital and reserves is, therefore, a distinction without difference. Borrowed capital, again, is created out of past savings which are lent to the company on fixed rates of interest. Thus capital employed representing share capital, reserves and borrowings is all out of savings of the community in one form or the other, all ranking for a return and thus having the potential for capital growth.

Capital generation, however, is not achieved by distributing all the profit earned to the shareholders through dividends although they may welcome it, in which case much of the profit so distributed would conceivably go for personal consumption rather than for capital formation. Hence, it is that the companies tend to issue bonus shares so as to enable at least a portion of surplus earned in business to be ploughed back, which thus serves the interests of the enterprise as well as the investor alike. "A given quantum of return, however," as stated by the Tariff Commission, as long ago as 1961, in its report on cement prices, "will enable different companies to declare different rates of dividend depending upon the composition of the capital employed (as between net worth and borrowings) and also of the net worth (as between Share Capital and Reserves). Hence, in any scheme of remunerating the Industry, **the return available as a percentage of net worth should,** in our view, **be the more equitable basis than what the dividends can be declared."**

It is necessary to note that the capital employed basis of computing the return does not reflect clearly the adequacy or otherwise of the

TABLE 1 : BULK DRUGS

	Alternative A	Alternative B	Alternative C
Assumptions :			
Capital employed/Turnover ratio	1:1	1:1	1:1
Equity Debt ratio ..	1:Nil	1:1	1:2
Turnover	100	100	100
Capital employed ..	100	100	100
Consisting of :			
Shareholders' funds ..	100	50	33
Borrowings (debt) ..	Nil	50	67
Rate of return—12% **Post-Tax,** on Shareholders' Funds OR 20% Before Tax, Inerest & Bonus on Capital Employed.			
Return on Capital employed			
@ 20%—(pre-tax etc)	20.00	20.0	20.0
Less : Interest @ 15%	Nil	7.5	10.0
Less Bonus	3.00	3.0	3.0
Balance	17.00	9.5	7.0
Less: Tax @ 60% ..	10.02	5.7	4.2
Profit after tax	6.08	3.8	2.8
Post-tax return 12% on Equity	12.0	6.0	4.0

Return to the shareholder, insofar as it is related to gross profits, from out of which not only dividends but also interest payments on borrowed capital, tax provision, etc. are made. Thus, the 15 per cent. return on capital employed currently in vogue for bulk (based on the financial structure of 34 companies of the industry in 1965-66, as computed by the Tarff Commission, which was, then composed of 42 per cent. of share capital, 37 per cent. of reserves and 21 per cent. of long term borrowings) really means a 6 per cent. profit, **after tax**, on the capital employed (assuming a tax

(rate of 60 per cent.); out of this return 8.5 per cent. on paid-up capital i.e. 3.6 per cent. of capital employed) goes out as dividend and thus, only 2.4 per cent. on capital employed is retained by the industry for future growth. To the shareholder, however, the correct yardstick of return is the ratio of profit to owned funds (i. e. paid-up capital and reserves) known as net worth—which is net of all outgoings. Thus, based on the same financial structure of the industry as in 1965-66 computed by the Tariff Commission, the return on net worth comes to only 7.6 per cent. How unrealistic and inadequate such a rate of return could be seen from the fact that the Unit Trust of India, for example, has been declaring a dividend of over 8.5 per cent. for some years now, while the long-term fixed deposits in nationalised Banks fetch up to 10 per cent. and in good companies anywhere between 12 to 15 per cent.

Thus, the adequacy of the return should be judged not by legal provisions alone but by the alternative opportunities available for investment. The Tariff Commission had measured the return to the shareholder in terms of the dividend paid to him alone, which is, however, irrational and incorrect as well, insofar as reserves which represent the savings of the community as much as paid-up capital, are also used in business and are, thus, entitled to a return. In fact, in the financial structure of the Industry as computed by the Tariff Commission, if the proportion of paid-up capital and reserves had been different, the total capital employed remaining the same, it would have come up with a different recommendation as regards Return. In any case, it is facile to assume that the same financial structure would remain unaltered for ever, especially in the context of the declining investment in the Industry in recent years. Thus, the financial structure of the industry, as compiled by "The Economic Times" in respect of 40 drug and pharmaceutical companies, for the year 1972-73. reveals an altogether different composition of the capital employed. the ratios being 31.1 per cent. for share capital, 36.3 per cent. for reserves and 32.6 per cent. for borrowings. In other words. the ratio of owned funds (share capital and reserves) to borrowings in the industry is seen to have become very much less in 1972-73 (2:1) compared to the year 1965-66 (when it was roughly 4:1). This again goes to confirm that the return available to the industry for plough-back, in terms of owned funds, is becoming less and less progressively.

The Hathi Committee, viewing all these anomalies and distortions

and having regard to the need for quick and substantial investment, especially in the field of bulk drugs, has evolved the concept of **post-tax** return on capital, which takes into consideration what for a shareholder is the most relevant profit indicator, namely return on owned funds (paid-up capital and reserves). Depending upon the importance and complexity of the bulk drug, a **post-tax** return between 12 and 14 per cent on equity (paid-up capital and reserves) has been recommended as a basis to be adopted in price fixation. The Committee added: "For the purpose of determining the rate of Return on this basis, taxation should be calculated on the basis of statutory rate of tax. Otherwise the benefits of any specific corporate tax concession will be denied to the units in the industry." Taxation really is an outgoing like any other expense and even in other countries where there is profit control in certain industries, it is seen that such control operates only on an **after-tax** profit basis. That the post-tax return on capital is better from the angle of attracting investment, than the pre-tax basis, as hitherto followed is illustrated by the exercise in Table 1.

The **post-tax** return of 12 per cent on equity is thus seen to be better than the **pre-tax, pre-interest and bonus** return of 20 per cent on capital employed.

The Committee has also recommended, and rightly, to exempt from price control bulk drugs in which there are no imports and which, in terms of total sales, do not exceed Rs. 25 lakhs annually. Even in the matter of imported drugs, the Committee has catergorically stated that "as long as the country is dependent on net imports of a basic drug, the existing unit or a new unit may be free to determine the selling price provided it is not higher than the selling prices of STC which are based on average landed costs of imports and handling and other charges". It has also added significantly that if, for any reason, the production plans of the public sector or the wholly owned Indian units do not materialise, "other units in the industry including those with foreign equity participation may be permitted to set up production capacity". In the case of other bulk drugs, the Committee has recommended a system of price regulation based on detailed cost investigation, by which 'the price fixed enables an efficient manufacturer to get a return on his capital employed which is a little higher than is available on formulations for the industry as a whole".

All these recommendations taken together are highly rational and

progressive in nature and, if given effect to properly, will certainly help to give a boost to the production of Bulk Drugs in the country.

(ii) **Formulation—profit-ceiling based on turn-over or equity:** The main thrust of the Hathi Committee's recommendations, in respect of drugs in general and formulations in particular, is **price regulation rather than price control** as such, based on a system of **selectivity** for groups of products instead of on an individual product basis. As it is, the present system of price regulation extends to over 6,000 packs distributed amongst 2,500 products. In view of the cumbersome nature of this work and the enormous administrative burden involved, the Hathi Committee has justifiably recommended the exemption, from the purview of price regulation, of all units with a turn-over of less than Rs. 1 crore as against the present limit of Rs. 50 lakhs.

In view, however, of the possibility that units with a turn-over of less than Rs. 1 crore may also be producing important drugs and formulations, the Committee has recommended that all drugs and formulations with an all-India sale of Rs. 15 lakhs should be kept under price control. By this means, it is expected, that the product coverage may go down by nearly 80 per cent. and yet, the controlled sector would account for 70 per cent. of the total turn-over of the Industry. In respect, however, of 117 medicines identified by the Committee as essential for mass consumption, it has said that "the policy objective should be to ensure that prices are fair and reasonable to the producer and to the consumer. But this will need to be supplemented by appropriate action to strengthen the production base by ensuring adequate supplies of materials, both domestic and imported. This is an unexceptionable statement indeed.

Another suggestion of the Committee is that two or three market leaders which between them account for over 60 per cent of the total sales of a product should be identified and the maximum prices prescribed for these products, so that other units could follow or be made to follow these price norms. "This particular variant of selectivity", in the words of the Committee, "may be administratively simpler". Above all, based on the Tariff Commission's approach and later followed by the Wanchoo Committee which suggested a graded ceiling on profits as a percentage of turn-over and taking into account the recent increase in the cost of inputs, bank rates, etc. the Hathi Committee has recommended a *profit ceiling* in respect of the formulation activity, in the range of 8 to 13 per cent. of sales turn-over or, alterna-

tively 10 to 12.5 per cent. *post-tax* on net worth. This alternative of Return based on equity after taxes has been suggested so as to ensure that the recommended profit ceilings do not work to the disadvantage of units, particularly in the indigenous sector.

Thus, both in respect of bulk drugs and Formulations, the concept of *post-tax* return has been accepted, which is, indeed, heartening insofar as it breaks new ground in the field of Price Control and is bound to prove beneficial to the industry in attracting new investment and promoting its growth all round. Current indications are that while a *post-tax* Return of 14 per cent. on equity may be fixed for bulk drugs, for formulations a ceiling of not more than 5 per cent. on turn-over is favoured. In view of the higher capital-turnover ratio in the formulation activity, it is perhaps felt that the Hathi Committee's profit ceilings for formulations are rather on the high side.

The industry, however, while broadly agreeing with the recommendations of the Hathi Committee, has made certain suggestions to introduce greater flexibility. Thus, it has suggested the exemption from price control of those drugs in which there are many competing units, so that price reduction through competition and self-regulation may be brought about, which is considered the more enduring and healthy means of attaining the objective. Thus, in respect of the 117 products identified by the Hathi Committee as essential for mass consumption and virtually almost all of which are presently produced by the organized sector with foreign collaboration, it is felt that, except for 30 or so non-prescription items of this list, the rest should be decontrolled, allowing the market forces to operate and providing, at the same time, for a self-regulatory control on profit at 5 per cent. *post-tax,* on turnover.

Be that as it may, as the Hathi Committee has rightly stated, "while the operation of price control on drugs and pharmaceuticals has helped in preventing the emergence of very large or excessive profits by the industry, the more important longer term problem of evolving arrangements to ensure that the drug industry operates in a framework which ensures the adequate supplies of essential drugs and pharmaceuticals at prices which are fair and equitable both to the producers and to the consumers, however, still remains". In this context, the principle of *selectivity* in Drug Pricing advocated by the Committee, with its *stress on price regulation more than on price control* as such, is a welcome new departure from the conventional methods of pricing and is bound to prove beneficial to all concerned—the producer, the

consumer and the community at large—if only the recommendations in this regard are properly implemented.

Rationalisation of the price structure, however, will be possible only if both the Government and the Industry lend a helping hand. The former can help by reducing considerably, if not eliminating altogether, the *cost of delay* in taking decisions on price revisions, conversion and packing norms, by reducing excise and other levies currently imposed on drugs and formulations, and above all, by simplifying procedures for licensing and expansion and for import of essential raw materials, especially in the matter of the canalised items which should be made available more easily and cheaply than now. The Government has already exempted from excise duty products marketed under pharmacopoeial names, with a view to keeping the prices of drugs down. What seems necessary is to exempt such products from excise duty, irrespective of the label or packing employed. It is estimated that as much as between 20 to 25 per cent of the retail price is accounted for by Union and State levies of various kinds—Customs, excise, sales-tax, Akbari duties etc. As the gross product of the pharmaceutical industry is less than 1 per cent of the GNP, it would seem safe to postulate that the elimination of all excises, duties and sales-tax related to essential medicines would reduce total Government revenues by only a fraction of one per cent. To retain such levies, however, is tantamount to taxing the patient for being sick!

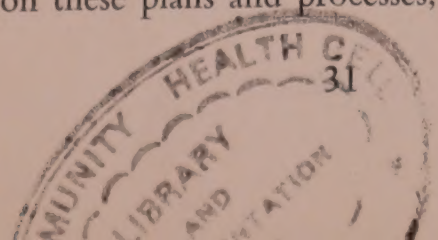
This brings us to the question of norms of conversion costs and packaging charges for the various categories of pharmaceutical products. Variations in these costs occur due to variations in the price levels of consumer stores, services, etc. and also due to increases in wages and salaries which together are estimated to constitute about two-thirds of the conversion costs. It would, therefore, seem fair and appropriate that the price regulating mechanism allows increases or decreases in conversion and packing norms in keeping with the variations in the cost of living index, instead of the present *notional* increase of 5 per cent. per annum allowed on the basis of 1969-70 data which, however, have no relation to present realities. Incidentally, such an automatic provision made in the pricing system would also eliminate the need for detailed cost investigations from time to time and thus, save considerable time and effort, indeed, in the BICP at Delhi.

Another question which often seems to create problems is the level of mark-up allowed and necessary for the formulated drugs of various kinds. The mark-up is meant to cover expenses defrayed on trade

commission, outward freight, selling and distribution expenses, interest, bonus to employees, R & D expenses etc. and also a reasonable margin to the producer. A study conducted in this regard has reportedly revealed that a drug unit's *break-even point* is reached at a mark-up level of about 75 to 80 per cent. of its manufacturing cost. A rational relationship, thus, seems necessary between the profit ceiling imposed and the levels of mark-up actually allowed in the case of different groups of formulations.

A word is perhaps necessary here regarding the brand names, insofar as they have a bearing on the cost and price structure of drugs and pharmaceuticals. Based on the recommendation of the Hathi Committee, the Government of India is reportedly contemplating an experimental abolition of brand names in the case of five products to start with, namely, ferrous sulphate, aspirin, chlorpromazine, analgin and piperazine. While the industry vehemently opposes the move on the ground, among other things, that brand identification is the only means of ensuring quality assurance of products and preventing the growing menace of spurious and sub-standard drugs in the country, there is an equally strong view, on the other side, that brand abolition is the only way by which the stranglehold of the market by the foreign drug firms could be prevented, and thus a drastic reduction in the promotional and other costs of these products could be brought about, without affecting legitimate profitability. There is perhaps something to be said in both the view-points and that is probably why the Hathi Committee itself has cautioned against any hasty move against brand abolition, especially in the context of the experience of Pakistan and other countries where the experiment is reportedly not much of a success. There is, however, no denying the fact that the consumer's motivation and preference are for "brands" which are identified with quality and reliability. For the same reason, it casts a great responsibility on the Industry as well to ensure that the "branded" products are reasonably priced.

Above all, it is vital that stringent measures are taken to ensure that only quality drugs are produced, irrespective of whether the units are small-scale, medium-scale or large-scale. Detailed model plans should be prepared for manufacturing units, especially for the medium and small-scale entrepreneurs, to provide for all types of operations commonly required in production as, for example, tableting, capsulating, liquid orals, injections, etc. The manufacturer concerned may certainly improve upon these plans and processes, but the model is the mini-



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mum to which he should adhere. In this way, not only the system could be rationalized and standardised leading to increased public confidence in the drugs produced in such units but also inspection will be simplified, cutting down red-tape and other maladies in the process.

Finally, it is necessary to stress that the public sector drug units which have been assigned a commanding role to play in drug production, especially in the field of bulk drugs, should play an increasingly important and responsible part in fully utilising their production capacity, without pre-empting it as hitherto, while the multinationals who are certainly capable and have the technology should be allowed to contribute in areas best suited to them, namely, technology transfer in a way beneficial to the country as a whole. Great opportunity, indeed, awaits them in updating the technology available in the country, on which depends, in the final analysis, the economic production of bulk drugs and consequently, of formulations as well. In this context, therefore, there is ample scope for all the different sectors of the industry—indigenous and foreign, public and private, large and small—to work in a mutually complementary manner, without any confrontation whatsoever between them. The drug industry, indeed, as has been rightly said, is "a complex industry, and problems of health and disease are still more complex. No cut and dried solutions can be presented for resolving these problems, but it is only with the active co-operation and understanding of the problems facing the country on the part of the Industry, Governmental authorities, physicians and patients that some attempt can be made to lessen the burden of ill-health".

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